

REMARKS

With this response claims 1-39 are pending. Claims 1 and 16 have been amended. Claims 1-39 remain for consideration.

No fee is believed to be due at this time.

Reconsideration and allowance of the claims, as amended and in view of the following remarks, are respectfully requested.

35 U.S.C. §112

First paragraph

The Office action rejects claims 1-39 under 35 USC §112, first paragraph, as containing subject matter said to be not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office Action states that it is not clear 1) how the adhesive extends below the finger cot and 2) what the barrier, the barrier layer, or the membrane are in reference to. The Office action further states that the specification does not recite any support for these structural limitations.

With respect to the first rejected language relating to adhesive extending below the finger cot, Applicants refer to the text of the original specification, e.g., at paragraph 27, page 6. At paragraph 27, the specification describes an embodiment of the invention wherein an adhesive backing covers a portion of a patient side of a drape from about the level of a pouch, below a finger cot, to nearly the top of the patient side of the drape. This written description is clear and would be easily understood by one of skill to include adhesive located at a top (upper) portion, near a top edge of a drape, and below the finger cot, on the patient side of the drape. See also figure 3 as amended. Thus, the application as originally filed includes clear and express written description, e.g., at paragraph 27, of adhesive extending below the finger cot, on the patient side of the drape, in a manner that would allow one of skill to produce such a drape. The rejection of this language under section 112, first paragraph, as lacking a clear written description or enablement under section 112, first paragraph, should be withdrawn.

In response to the other rejected language, the terms “barrier,” “barrier layer,” and “membrane,” are also described and enabled in compliance with the first paragraph of section 112. The specification, throughout, describes a drape that includes a flexible finger cot that allows examination of a second orifice (rectum), e.g., during a urologic exam, a gynecologic exam, an obstetric exam, or the like, such that the cot provides a physical barrier to the rectum. See, e.g., paragraph 10:

[T]he cot provides a physical barrier between the rectum and the finger and between the rectum and the vagina.

In various embodiments, the cot can be constructed of the same material as the drape, or of a material that is more flexible than the balance of the drape. Regardless, the flexible cot functions as a barrier to the rectum. See also paragraph 33, which includes the following written description:

If it is desired to conduct a subsequent rectal examination, the physician may do so by placing his or her finger into the finger cot 22, and subsequently placing his or her finger and the finger cot 22 into the rectum of the patient. It is not necessary to remove and discard gloves used during the vaginal examination prior to conducting the rectal examination.

Overall, the specification is clear in its express written description of a cot that can allow examination of a rectum while acting as a physical barrier in the form of, e.g., a flexible film or membrane. One of skill would so understand and be able to practice this subject matter according to the written description of the specification, and the rejection under section 112, first paragraph, should be withdrawn.

Second paragraph

Claims 1-26 and 28-39 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. The Office action states that in claims 1, 16, 28, 30, and 34, it is not clear as to what the barrier layer, physical barrier, barrier, membrane, and barrier, respectively, are in reference to.

Applicants have amended claims 1 and 16 to more clearly define the claimed subject matter. Claims 1 and 16 now recite that the finger cot provides a “barrier”

between the second orifice (e.g., rectum) and probe (e.g., finger). As explained above with respect to the section 112, first paragraph, rejection, the term "barrier" refers to a functional property of the finger cot that can be in the form of a flexible film or membrane. A cot that provides such function is described by the original specification, for example, at page 5, paragraph 24, and at page 8, paragraphs 33 and 34, and in the figures.

In view of the above comments and amendments, Applicants request that the rejection be withdrawn.

35 U.S.C. §102

The Office action rejects claim 1 as being anticipated by U.S. Patent No. 5,445,165 (herein referred to as "Fenwick").

The rejection is traversed.

The Office action cites Fenwick as anticipating claim 1 by describing a device comprising a sheet 10, of flexible material having an aperture 13, an adhesive backing 38, and a finger cot 14. This fails to identically teach, i.e., anticipate, every element of claim 1.

Claim 1 recites a device comprising a sheet having an aperture, and an adhesive backing "proximate said aperture."

Fenwick does not teach an adhesive backing that is proximate said aperture. The adhesive strips 38 taught by Fenwick are positioned on the drape a significant distance from upper fenestration 13 (aperture). Thus, they are not "proximate said aperture" as recited in claim 1. Fenwick also identifies adhesive strips 46, but these do not constitute an adhesive backing as recited in claim 1.

Applicants respectfully request that the rejection of claim 1 as anticipated by the Fenwick reference be withdrawn, because the Fenwick reference does not teach all of the elements recited in claim 1, and therefore cannot be said to anticipate claim 1.

35 U.S.C. §103

Fenwick and Thomalla, claims 14-16

The Office action rejects claims 14-16 under 35 USC §103(a) as being unpatentable over Fenwick in view of U.S. Patent No. 5,388,593 (herein referred to as “Thomalla”).

The rejection is traversed.

All of claims 14-16 include a feature of an adhesive backing proximate to an aperture. The Fenwick reference is discussed above and explained to not identically teach an adhesive proximate to an aperture. Fenwick also does not suggest a surgical article that comprises an adhesive proximate to an aperture. Thus, Fenwick by itself fails to teach or suggest the subject matter of claims 14-16. The rejection is therefore based on a combination of Fenwick with Thomalla.

Thomalla fails to remedy this shortcoming of Fenwick. Thomalla describes a surgical drape having adhesive strips 34 and 36 (column 4, lines 30-40) located at the upper end 14 and lower end 16, respectively, of the drape. As with Fenwick, Thomalla does not specifically teach or suggest an adhesive backing that is proximate to the aperture. Figure 1 of Thomalla shows adhesive strips 34 and 36 and adhesive tabs 38, none of which is proximal to aperture 50. Therefore, Fenwick or Thomalla, taken alone or in combination, do not describe a medical device having all the elements as described in any of claims 14-16, and the rejection of these claims over this combination of references should be withdrawn.

Fenwick and Taylor, claims 2, 3, 5, 9, 10, and 13

Claims 2-3, 5, 9-10, and 13 are rejected as being unpatentable over Fenwick in view of U.S. Patent No. 5,419,343 (herein referred to as “Taylor”).

The rejection is traversed.

All of claims 2, 3, 5, 9, 10, and 13 include a feature of an adhesive backing proximate to an aperture. The Fenwick reference, as previously discussed, does not include a teaching or suggestion of an adhesive backing proximate to an aperture.

Taylor fails to remedy this shortcoming. Taylor is not seen as describing an adhesive backing proximal to an aperture, as recited in claims 2, 3, 5, 9, 10, and 13. Therefore, Fenwick or Taylor, alone or in combination, fail to teach or suggest a medical device as recited in any of claims 2-3, 5, 9-10, and 13, reciting an adhesive backing proximate to an aperture. The rejection of these claims as obvious over the cited references should be withdrawn.

Fenwick, Taylor, and Neal, claim 4

The Office Action rejects claim 4 as being unpatentable over Fenwick in view of Taylor and further in view of U.S. Patent No. 4,570,628 (herein referred to as "Neal").

The rejection is traversed.

Claim 4 includes a feature of an adhesive proximate to an aperture. The Fenwick and Taylor references, together or separately, do not include a specific description of an adhesive backing proximate to an aperture.

The Neal reference fails to remedy this shortcoming of Fenwick and Taylor. Neal describes a surgical drape with a collection pouch that has volumetric measuring means (column 1, lines 60-65). Neal does not describe an adhesive backing proximal to an aperture, as recited in claim 4. Therefore, Fenwick, Taylor, or Neal, taken alone or in combination, fail to describe a medical device having all the elements as described in claim 4, including an adhesive backing proximate an aperture. The rejection of claim 4 as obvious over the cited references, should therefore be withdrawn.

Fenwick and Baker, claims 6 and 7

The Office action rejects claims 6-7 as unpatentable over Fenwick in view of U.S. Patent No. 5,979,450 (herein referred to as "Baker").

The rejection is traversed.

Claims 6 and 7 recite a feature of an adhesive proximate to an aperture. The teachings of Fenwick have been described above and do not include a specific description or any suggestion of an adhesive backing proximate to an aperture.

The Baker reference fails to remedy this shortcoming of Fenwick. The Baker reference is not seen to describe an adhesive proximate to an aperture, as recited in claims 6 and 7. The Office action fails to identify how or where the Baker reference is believed to provide a teaching or suggestion, combined with a motivation, that would have led one of skill to place an adhesive backing proximate to an aperture in a surgical drape, based on the cited references. Therefore, Fenwick or Baker, taken alone or in combination is not seen as teaching or suggesting a medical device as recited in claim 6 or 7, and the rejection of these claims as obvious over Fenwick and Baker should be withdrawn.

Fenwick and Neal, claims 11 and 12

The Office Action rejects claims 11 and 12 as being unpatentable over Fenwick in view of Neal.

The rejection is traversed.

Claims 6 and 7 recite a feature of an adhesive proximate to an aperture. The Fenwick reference, as discussed above, does not include a specific description or any suggestion of an article as claimed, having adhesive backing proximate to an aperture.

The Neal reference fails to remedy this shortcoming. As discussed above with respect to the rejection of claim 4 in view of Fenwick and Taylor and Neal, the Neal reference does not describe or suggest an adhesive backing proximal to an aperture. Therefore, neither Neal nor Neal in combination with Fenwick and Taylor can be said to teach or suggest a medical device as recited in claims 11 and 12, including an adhesive backing proximate an aperture. The rejection of claims 11 and 12 as obvious over the cited references should be withdrawn.

Allowable Subject Matter

Applicants note with appreciation the Examiner's indication that claims 16, 27-28, and 34, would be allowable if rewritten or amended to overcome the rejections under 35 USC §112, second paragraph, and that claims 8, 17-26, 29-33 and 35-39 would be allowable if rewritten to overcome the rejections under 35 USC §112, second paragraph, and to include all of the limitations of the base claim and any intervening claim.

Applicants submit that the claims in their amended forms overcome the asserted rejections. Applicants believe that patentability extends to all of the pending claims. In view of the present amendments and remarks provided herein, Applicants submit that the rejections have been either overcome or should be withdrawn and request that a notice regarding the allowability of all pending claims be issued.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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